

U.S. Patent Application No. 10/088,750  
Response To Restriction Requirement dated December 16, 2004  
Reply to Office Action of November 16, 2004

**REMARKS**

In the Office Action of November 16, 2004, the Examiner set forth a restriction requirement between the following groups:

Group I, claims 1 - 6, 9 - 15, 18 - 25, 28, and 29 drawn, in part, to an RNA higher structure having a function for promoting a translation activity which comprises a base sequence containing SEQ ID NO: 1 - 6 or 7, or a related sequence; a recombinant vector containing a polynucleotide comprising at least one base sequence, a transformant that has been transformed with the recombinant vector, a method for synthesizing a heterologous protein utilizing a polynucleotide comprising at least one base sequence, a method for synthesizing a heterologous protein utilizing a recombinant vector containing a polynucleotide comprising at least one base sequence, a method for synthesizing a heterologous protein utilizing a transformant which is transformed with a recombinant vector containing a polynucleotide comprising at least one base sequence, or a method for initiating synthesis of an arbitrary heterologous protein using a polynucleotide comprising a base sequence, or a method for synthesizing a polynucleotide encoding the heterologous protein and a polynucleotide that promotes translation activity and has an RNA higher-order structure, where the protein synthesis is carried out in a cell, and

Group II, claims 5 - 11, 13, 15 - 17, and 20 - 27, drawn, in part, to a method for synthesizing a heterologous protein utilizing a polynucleotide comprising the least one base sequence having a RNA higher order structure, a method for synthesizing a heterologous protein utilizing a recombinant vector containing a polynucleotide comprising at least one base sequence having an RNA higher structure or a method for initiating synthesis of an arbitrary heterologous

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protein using a polynucleotide comprising a base sequence, or a method for synthesizing a polynucleotide encoding the heterologous protein and a polynucleotide that promotes translation activity and has an RNA higher-order structure, where the protein synthesis is carried out in a cell-free system.

In response, the Applicants elect Group II, with traverse.

The restriction is traversed for the following reasons. Since the application is a national phase filing of an international application, restriction is governed by the unity of invention standard set forth in PCT Rule 13. See, for example, MPEP 1893.03(d). Under the PCT rules, there is unity of invention, and a restriction is improper, if there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features that define a contribution over the prior art.

The inventions claimed in the present application clearly meet the standard for unity of invention. In particular, the claimed inventions commonly relate to the discovery that RNA molecules that have a higher order structure having at least pseudoknot I, II and III structures can function to promote translation activity. All of the pending claims contain this feature, including the claims that specifically refer to the sequences of SEQ ID NO:1-7. Regarding the method claims, claims 5 - 11, 13 - 17, and 20 - 29, these claims clearly satisfy the requirements of unity of invention regardless of whether a protein is synthesized in a cell or in a cell-free system. In particular, all of the method claims are linked by a single general inventive concept under Rule 13 of the PCT in that they involve at least one common or corresponding technical feature, the use of RNAs having a specific higher order structure to initiate and promote translation activity. This common technical feature defines a contribution that the claimed invention makes over the

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prior art. Moreover, the claims directed to the RNA higher-order structure (claims 1 - 2), the recombinant vector (claim 3 and 18), and the transformants (claims 4, 12, and 19) have unity of invention with the method claims under the PCT rules, since they all share the same technical feature, the RNAs having the higher order structure having at least pseudoknot I, II and III structures, which structure is specifically designed for carrying out the method of translating proteins by serving to initiate translation.

Further, it is respectfully submitted that if a proper search is conducted with respect to a method of cell-free protein synthesis wherein protein synthesis is initiated by a polynucleotide having an RNA higher order structure having at least pseudoknot I, II, and III structures, it would not be a serious burden for the Examiner to extend the search to include a method of protein synthesis using the same polynucleotide as a protein synthesis initiator in a cell. Moreover, it would not be a serious burden for the Examiner to extend the search to include the RNA higher-order structure itself, and the recombinant vector and transformants containing the RNA higher-order structure, particularly since the RNA higher order structure would have been included in a thorough search of the methods of protein synthesis.

Accordingly, the restriction should be withdrawn and all of the claims of Group I and Group II should be examined together.

The Examiner further required that one nucleotide sequence from SEQ ID NO: 1-7 be selected. In response, Applicants elect SEQ ID NO: 1, with traverse.

The Examiner stated that the requirement to elect one nucleotide sequence from SEQ ID NO:1-7 is not a species election (implying that the requirement is a restriction). However, this characterization of the election requirement is clearly an error. The Examiner has not clearly set

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forth a restriction in the present Office Action between the nucleotide sequences, since the restriction has been drawn only between Group I and Group II as noted above. Accordingly, the requirement to elect one nucleotide sequence from SEQ ID NO: 1 - 7 should properly be treated as an election of species and not a restriction. If the Examiner intends to treat the requirement to select one nucleotide sequence from SEQ ID NO: 1-7 as a restriction and not an election of species, the requirement is respectfully traversed for the following reasons.

The Examiner alleges that the claims containing different sequences do not have in common the same or corresponding technical features. The Examiner further alleges that each nucleotide sequence is directed to a distinct sequence containing an RNA higher order structure and that the claims are not so linked by a special technical feature within the meaning of PCT 13.2 so as to form a single inventive concept and that lack of unity is proper. The Examiner's position regarding sequences of SEQ ID NO: 1-7 is clearly in error.

As noted in the previous response, a restriction between the individual sequences of SEQ ID NO:1 - 7 is clearly inappropriate under the PCT standard of unity of invention, since all of the RNAs of SEQ ID NO:1-7 are linked by a special technical feature within the meaning of PCT 13.2 so as to form a single inventive concept. In particular, all of the claims, whether they describe the polynucleotide generically or whether they relate to the specific sequences of SEQ ID NO:1-7, require an RNA higher order structure including at least the pseudoknot structures (PK I, PK II and PK III). All of the RNAs represented by SEQ ID NO: 1 - 7 share this common higher order structure and further share four stem-loop structures (ST III, ST IX, ST V and ST VI). As shown in Figure 4, this common higher order structure of the RNAs represented by SEQ ID NO: 1 - 7 can be correlated to corresponding complimentary loop-forming domains in the

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linear sequence of the RNAs.

Accordingly, the group of generically defined polynucleotides, as well as the RNAs represented by SEQ ID NO: 1 - 7 clearly have both a common structure, the higher order structure that includes the pseudoknot structures (PK I, PK II and PK III), and clearly have a common activity, the promoting of translation activity when the polynucleotide is coupled to a polynucleotide encoding a heterologous protein. Therefore, the group of generically defined polynucleotides having the higher order structure, as well as the RNAs represented by SEQ ID NO: 1 - 7, are clearly linked by a special technical feature to form a single inventive concept as required by Rule 13.2 and clearly meet the requirement of unity of invention.

Further, it is respectfully submitted that the remaining SEQ ID NO: 2-7 can be examined together with SEQ ID NO:1 without a serious burden to the Examiner, since the sequences are all relatively short in length.

Accordingly, if the Examiner considers the requirement to elect one of the sequences of SEQ ID NO:1 to be a restriction and not an election of species, the restriction should be withdrawn and all of the sequences of SEQ ID NO:1-7 should be examined together.

### Conclusion

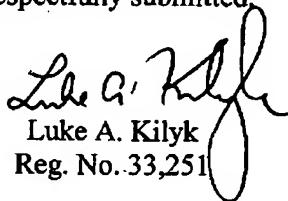
In view of the above discussion, it is respectfully requested that the Examiner withdraw the restriction requirement of November 16, 2004 and examine all of the embodiments of Claims 1 - 29, including both methods of cell-based protein synthesis and methods of cell-free protein synthesis and examine all of the embodiments of SEQ ID NOs:1-7.

If there are any other fees due in connection with the filing of this response, please charge

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the fees to Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,



Luke A. Kilyk  
Reg. No. 33,251

Atty. Docket No. 3190-015  
KILYK & BOWERSOX, P.L.L.C.  
53 A East Lee Street  
Warrenton, VA 20186  
Tel.: (540) 428-1701  
Fax: (540) 428-1720